

Sequential Therapy versus Standard Triple-Drug Therapy for *Helicobacter pylori* Eradication

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The full report is titled “Sequential Therapy versus Standard Triple-Drug Therapy for *Helicobacter pylori* Eradication. A Randomized Trial.” It is in the 17 April 2007 issue of *Annals of Internal Medicine* (volume 146, pages 556-563). The authors are D. Vaira, A. Zullo, N. Vakil, L. Gatta, C. Ricci, F. Perna, C. Hassan, V. Bernabucci, A. Tampieri, and S. Morini.

What is the problem and what is known about it so far?

Helicobacter pylori (*H. pylori*) is a common type of bacteria that usually infects people during childhood. In almost 50% of cases, the infection does not cause symptoms. However, some people with *H. pylori* infection eventually develop inflammation of the stomach (gastritis) or ulcers in the stomach or upper small intestine. Gastritis and ulcers cause abdominal pain and, sometimes, bleeding. Doctors often treat stomach pain and ulcers caused by *H. pylori* with a combination of several antibiotics that are given for several days. Treatment gets rid of *H. pylori* in most patients, but 15% to 30% of patients may have persistent infection despite treatment. In recent years, there has been increasing resistance to standard antibiotic treatments for *H. pylori* infection. This means that it is harder to get rid of *H. pylori* in some patients and that we need new treatment regimens.

Why did the researchers do this particular study?

To see whether giving 4 antibiotics in sequential order gets rid of *H. pylori* infection more often than does a standard regimen of 3 antibiotics.

Who was studied?

300 adults with *H. pylori* infection and stomach pain (dyspepsia) or peptic ulcers.

How was the study done?

Patients were randomly assigned to receive either a sequential regimen or a standard regimen (the standard regimen is approved by the U.S. Food and Drug Administration). The sequential regimen was pantoprazole, amoxicillin, and placebo for 5 days followed by pantoprazole, clarithromycin, and tinidazole for 5 days. The standard regimen was pantoprazole, clarithromycin, and amoxicillin for 10 days. Four and 8 weeks after treatment, all patients were checked for *H. pylori* infection with urea breath tests. If the results of both tests were negative, researchers concluded that the infection was cured or eradicated. They then compared cure rates between groups. During the study, researchers, doctors, and patients did not know which treatment each patient received.

What did the researchers find?

The cure rate of *H. pylori* infection was greater with the sequential regimen (91%) than with the standard treatment (78%). Both regimens caused a few side effects. About 5% of patients in each group had stomach discomfort and 3% to 5% had mild diarrhea.

What were the limitations of the study?

The sequential treatment included 1 more drug (tinidazole) than did the standard treatment. It is hard to know whether that drug or the sequential administration of the drugs led to improved outcomes. The study was conducted in Italy. Other countries may have different rates of resistance to particular antibiotics. The antibiotic regimens in this study might have varying success rates in countries that have different resistance patterns.

What are the implications of the study?

A 4-drug sequential regimen got rid of *H. pylori* infection more often than did a standard 3-drug regimen.

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